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PRINCIPAL INVESTIGATOR: David John Doukas, M.D.

CONTRACTING ORGANIZATION: University of Michigan
Ann Arbor, Michigan 48109-1274

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David John Doukas, M.D.

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

University of Michigan
Ann Arbor, Michigan 48109-1274

8. PERFORMING ORGANIZATION
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ddoukas@mail.med.upenn.edu

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

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The project, "Assessing Patient Values Towards Prostate Cancer Genetic Screening," has begun to determine the values, beliefs, and attitudes that influence a man's decision to undergo or defer genetic testing for prostate cancer risk. The project consists of two stages: (1) the completed **Focus Group Phase**, in which 12 focus groups of a total of 90 men have identified key values and beliefs regarding genetic testing for prostate cancer risk. These results have allowed for the construction of a draft survey instrument; and, (2) the **Survey Phase** in Years 2&3, in which the draft survey instrument will first be pilot tested, with final refinement afterwards, followed by a survey to be administered to 300 men recruited from the waiting rooms at three primary care sites. The survey will evaluate those relevant values, social factors, attitudes, and beliefs that are relevant to genetic screening for prostate cancer risk. As a result, this project will help better understand the decision making of men concerning genetic screening for prostate cancer risk, and will help health professionals who will counsel these men in the decision making process.

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INTRODUCTION

The project, “**Assessing Patient Values Towards Prostate Cancer Genetic Screening**,” is a two phase, 30 month study to elucidate factors relevant to men who are being offered the opportunity to undergo genetic testing for risk of prostate cancer. The project consists of two stages: (1) the **Focus Group Phase**, completed as of August 1, 1999, to identify key issues and insure the content validity of subsequent instrumentation, instrument design, and refinement; and, (2) the **Survey Phase** of men from the outpatient primary care setting who would be potential consumers of genetic screening in future efforts. Twelve focus groups of six to ten men have identified key values and beliefs regarding genetic testing for prostate cancer risk. A draft of the survey instrument has been constructed and refined. Pilot testing will occur in the second phase, followed by a survey administered to 300 men recruited from the waiting rooms at three primary care sites. The survey will evaluate those relevant values, social factors, attitudes, and beliefs that are relevant to genetic screening for prostate cancer risk. The goal of this project is to determine the values, beliefs, and attitudes that influence a man’s decision to undergo or defer genetic testing for prostate cancer risk. As a result, this project will help better understand the decision making of men concerning genetic screening for prostate cancer, and will, in turn, help health professionals who are counseling these men in the decision making process. Arming men with information on genetic screening targeted to their individual needs thereby allows them to better proceed through the informed consent process to understand genetic testing and its role in combating prostate cancer. An in depth appreciation of the reasons why men may want to avail themselves or avoid prostate cancer risk information will allow the disclosure process of informed consent to be tailored to benefit men individually. The promotion of genetic risk assessment as a tool aimed towards the individual — rather than using one generic method for the whole population — requires that we endeavor to assess individual values towards screening in the non-high risk population.

BODY

Background

The project, “**Assessing Patient Values Towards Prostate Cancer Genetic Screening,**” is ultimately intended to understand the decision making of men regarding genetic screening for prostate cancer risk, for use when genetic testing becomes available. As molecular genetic technologies are focusing on those genetic factors that predispose men for prostate cancer risk (e.g., the Hereditary Prostate Cancer 1 (HPC1) gene), there is a corresponding need to understand patients' values and beliefs about such screening.

Genetic testing for prostate cancer risk of presymptomatic men holds the promise of becoming an important tool in the control and the eradication of prostate cancer. Yet, its appropriate use is not well understood by patients or the majority of health care professionals to whom they turn for assistance. This innovative project will assess how, why, and when screening is considered by non-high risk men. By better understanding the motivations of such men when considering genetic screening for prostate cancer, we can anticipate their goals, concerns, fears, and objections as screening becomes more widespread. By observing the reasons why non-high risk patients elect or decline genetic screening for prostate cancer risk, we can better understand the values underlying these decisions regarding genetic screening in the general population. This process can lead physicians to more effectively work with patients, to help them overcome irrational fears, while respecting reasonable consideration leading to refusal.

Genetic testing for cancer susceptibility has evolved from the Human Genome Project. This form of risk assessment has great potential to reveal more about our future risks of prostate cancer and other health conditions than any other current screening modalities. By providing a map to our predisposition to disease, genetic screening may become a very powerful tool in preventive medicine (Nolan, 1988). Yet, the capability to offer genetic screening will likely generate new ethical quandaries for patients (Robertson, 1991; Doukas, 1991, 1993). While prostate cancer has been shown to have a genetic component, the degree of genetic versus environmental factors as influencing cancer development is uncertain (Grönberg, 1997). Although many are trying to identify HPC1, there is conflicting data as to its contribution to inherited forms of prostate cancer. McIndoe, et al., were unable to confirm linkage to chromosome 1q24-25 markers in an independent set of families (McIndoe, 1997). Also, there will likely be more than one HPC gene — similar to the situation in other common solid tumors like breast and colorectal cancer. As the gene loci for prostate cancer are identified, it is likely that genetic testing for prostate cancer risk will be developed.

It will be a matter of time and experience before genetic screening for prostate cancer risk will then move from the research to the clinical setting. Such testing may offer much as a tool for testing for prostate

cancer risk, but the potential impact on patients has not been evaluated. The ambiguity of the multifactorial nature of prostate cancer, and the degree to which genetics plays a salient role will therefore have a large impact on future genetic counseling and testing. Identification of a man at risk for prostate cancer (or his even becoming diagnosed) presents a dilemma without an unambiguous solution: should prophylactic surgery, increased surveillance (via PSA testing or rectal examination), or standard screening recommendations be followed by a man with a positive test result? The knowledge gained through screening may not necessarily lead to clear cut recommendations about what the patient should do with a positive test result.

The efficacy of established treatment options is not well established and the risk of treatment include incontinence and impotence (Gann, 1995; Krahn, 1994; CTFPHE, 1991). A risk of non-treatment is death. The patient's dilemma can be phrased in terms of extended life versus decreased quality of life. Many of the concerns in prostate cancer revolve around the concept of quality of life, a topic of pertinent consideration in prostate cancer screening (Shrader-Bogen, 1997; Cantor, 1995; Dougherty, 1994; Litwin, 1994;). At present, the risk of decreased quality of life is more tangible than the promise of extended life. The decision to test for genetic risk, then, initiates a set of decisions that have an inherent considerable uncertainty. The ethical response to such uncertainty is relevant, in that the weighing of benefit and personal choice considerations are not clear cut when the benefit to the patient is indeterminate. (Doukas, Feters, et al, 1997; Raffle. 1996; Wilkie, 1995; Neal, 1995) A critical omission in this theoretical discourse on the consequences of genetic screening has been the active participation from those who would be most affected — patients. The health provider's response needs to incorporate the relevant values of patients that help them formulate clinical decisions in this area of prevention.

Some fundamental concerns regarding genetic screening have been addressed elsewhere, e.g., the rights of the individual to informed consent and confidentiality, the obligations of health care providers to render beneficial treatment while minimizing harm, the ability of the government to allow for access to screening, and how it will be paid for (Murray, 1991; Elsas, 1990; Botkin, 1990; Davis, 1985; Walters, 1989). As a parallel to prostate cancer genetics research, authors in breast cancer genetics research have cited many relevant concerns from the genetics and mammography literature about why women would consider having genetic screening for breast cancer. Four main considerations emerge from this literature: (1) concerns about screening test validity (Lerman, 1997), (2) concerns over psychological impact (Baum, 1997; Croyle, 1997; Nowak, 1994), (3) ethical concerns, such as confidentiality and informed consent (Dickens, 1996), and (4) health behavior concerns, such as follow up counseling and surveillance (Burke, 1997; Healy, 1997; Parker, 1996). An initial attempt to evaluate such values was attempted by studying the potential benefits and negative consequences to BRCA 1 patients (Lerman, 1996). Lerman's research

findings beckon for an exploration of the many values that effect the screening decisions of men in genetic screening for prostate cancer risk.

Doukas has argued that the new genetic technologies will generate new ethical dilemmas involving the individual, and the relationships between him or her and the physician, the family, and society (Doukas, 1993). The relevance for prostate cancer screening is evident — patients requesting prostate cancer screening will bring to the health care provider a mixture of values, beliefs, social influence factors, and attitudes about screening and cancer. The patient will have a broad range of concerns and will ask themselves whether the screening should be done because of this cascade of consequences. We hypothesize that the ways men view their own values in screening for prostate cancer risk will be an important predictor of the choices that they will make. Understanding why men would consent or refuse genetic screening for prostate cancer risk necessitates the incorporation of the values, attitudes, and beliefs of the men who will use it. Eliciting these values can thereby provide a fuller description of why men would choose to have such screening. Such an understanding has been needed since a previous attempt by Pauker and Pauker used cost-benefit analysis for prenatal genetic screening (Pauker and Pauker, 1979; 1987). However, patients use other values outside of cost-benefit analysis to reach these difficult decisions (Lippman-Hand and Fraser, 1979; Beeson and Golbus, 1985). If medicine is to promote patient self-determination, a comprehensive assessment of values needs to be undertaken to develop any decision making model in this context (President's Commission, 1982). Values, such as those concerning aspects of religious, cultural, or philosophical beliefs, and the impact of social influence factors (e.g., spouse preferences) need to be more completely evaluated using both qualitative and quantitative methods to ascertain how men will make decisions on genetic screening for prostate cancer risk (Volk, 1997).

The purpose of this project is to evaluate those values that are most relevant in decision making in prostate cancer genetic screening, with the goal of formulating a model which will predict intention to seek testing. The project will evaluate non-high risk men from the primary care setting, without known increased risk for prostate cancer. Its ultimate aim is to provide basic data concerning the men's relevant values, beliefs, social influence factors, attitudes, and intention for screening; how they view the psychosocial assets and liabilities toward screening; and their relationship to other health related behaviors. One key feature of the project is our intention to develop a decision-making model, based on earlier work on medical decisions that explored motivations for screening in known high risk cancer populations. The resultant data will have immediate implications for counseling and public policy for primary care genetic screening — particularly regarding disclosure and comprehension needs in the informed consent process. This project will also measure several demographic characteristics to ascertain which characteristics are most predictive of intention to pursue genetic screening. The significance of education, religion, and other

philosophical values in respect to attitudes and intended behavior toward genetic screening will be assessed in this process. Specifically, the project advances the following hypothesis:

The Investigators hypothesize that a man's beliefs, attitudes, social influences, and demographic background will predict his intention to pursue genetic screening for prostate cancer risk. The concerns about the consequences of such screening are expected to be extensive in men without known high risk, particularly concerning the ethical and health behavior consequences, as well as global concerns about the reliability of the test. As part of this hypothesis, it is thought that family history for cancer and global cancer screening habits will play a part in the values and attitudes towards genetic testing for prostate cancer risk. By understanding the motivations of why men would want such screening and what barriers might preclude them, we can better approach men with the tools of disclosure to make sure that men understand the implications of their informed choice. When, how, and why men may or may not be receptive to prostate cancer genetic screening is likely to vary according to and individual's beliefs, attitudes, social influences, and demographic background. Understanding how these factors are relevant to genetic screening decision making will better equip physicians and genetic counselors on how to tailor the informed consent process to the needs of their patients.

Accomplishments to Date - Year 1

We have successfully met our objectives set out for the first year of the project. The empirical methods thus far have consisted of qualitative research using focus groups in the first completed phase, to be followed by quantitative research using survey techniques in the second phase (Years 2 & 3). The first phase of the project was conducted at the University of Michigan. The study was approved by the Institutional Review Board of the University of Michigan prior to any human subjects activity (#1998-028). These fulfilled goals of the project have been specified, using the Statement of Work Tasks as an outline:

Task 1: Identify relevant ethical issues for focus groups and construct probe questionnaire

The Focus Group Phase, was begun by Dr. Doukas' exhaustive literature review of the medical and bioethics literature. Dr. Doukas used Medline, the Internet, as well as from two on-site visits to the National Reference Center for Bioethics Literature at Georgetown University, to collect all salient writings on prostate cancer, genetic testing, and genetic counseling. These readings were extensively reviewed by all the investigators, after which a list of relevant moral, religious, and cultural themes concerning genetic testing for prostate cancer were articulated (see Appendix A). During this time, a firm well versed in

qualitative research, Personal Touch Marketing, was selected through a competitive bidding process to conduct the focus groups.

Tasks 2 and 3: Recruitment of Focus Groups/Conduct Focus Groups

The themes from the literature were then fashioned by the Investigators and Consultants into a Discussion Guide to be used with focus group participants, with a series of open-ended probe questions to elicit response. These materials were refined after the first focus group to further promote responses from the participants (see Appendix B). Twelve focus groups were recruited using a panel of men who identified themselves to PTM as willing to participate in Focus Groups, as well as through advertisements in local newspapers, and in postings at local churches and markets. The twelve groups of six to ten men each from the greater Washtenaw County area consisted of those without any known positive screening test for prostate cancer. We sampled men using stratifications of education (greater or less than two years of College), ethnicity (Caucasian, African-American, and Asian American), and by age (18-39, 40-54, 55-70). The participants received and signed a written informed consent before their participation. Of note, there were no reported adverse effects from the focus group discussion.

The men each participated for two hours of discussion and were audio taped as they participated in the focus group. Information on the nature of genetic testing for prostate cancer risk was reviewed with all focus group participants prior to discussion using a professionally videotaped presentation (written by the PI, with feedback from all Investigators and Consultants) to enhance conversations on values by focus group participants (see Appendix C). The broad spectrum of values, beliefs, and attitudes that are relevant to participants regarding prostate cancer genetic screening were then elicited in the focus groups by the moderator, William Pendry. The discussion was a lively interchange of questions and concerns on the utility and consequences of genetic screening for prostate cancer.

Task 4: Analysis of Focus Group Data

The proceedings of all groups were audio recorded and subsequently transcribed. The resultant data was then analyzed by the investigators to describe the spectrum of relevant themes and illustrative metaphors and quotations from the group. The data from the focus groups was analyzed to develop a list of values that emerged from the participants (see Appendix D). Responses from these focus groups were analyzed using the techniques

of immersion and crystallization (Crabtree and Miller, 1992) to ascertain relevant themes regarding how screening is viewed, how screening can be prepared for, and how test results could be discussed. The main themes that arose addressed the following issues: Beliefs of Consequences, Perceived Expectations, Benefits for Patients, Beliefs of Barriers, and Susceptibility Concerns. Each of these major themes consisted of a multitude of values-laden sub-themes that captured the essence of why men perceived prostate cancer genetic testing as a good or bad idea.

Task 5: Construct draft survey instrument

Quantification of those values most meaningful to focus group participants were then incorporated into a scaled survey instrument. Following classic psychometric theory and scale construction, the survey instrument was generated based on the major themes and subthemes identified in the Focus Group Phase. The draft questionnaire is illustrated in Appendix E.

Task 6: Member Checking of Focus Groups and Pilot Testing

The draft survey instrument's themes were reviewed with the focus group participants in the process of member checking, a process of validating the quantitative findings above. The themes were converted to a narrative format to maximize feedback (see Appendix F). Of the 90, requests for feedback in the member checking phase, 42 were returned. Of note, the respondents voiced support of the statements expressed in the feedback form and helped to express details on these statements. The analysis of these data is currently ongoing.

These activities of Phase One, i.e., the **Technical Objective 1** and its six **Tasks**, were completed on August 1, 1999, except for the pilot testing. Pilot testing of the survey instrument more appropriately will take place at the three Penn-affiliated outpatient practices in the Philadelphia area. This shift of location for the sub-task pilot testing (of Task 6) is very important in refining the questionnaire in the population where it will be administered.

CONCLUSIONS

While analyses are ongoing, some initial conclusions can be drawn from analyses completed to date. One important conclusion is that men are very favorably disposed to genetic testing for prostate cancer risk. Further, preliminary analyses appears to reveal that this effect is age related (i.e., increased support with age), and that there are ethnic differences regarding how much suspicion men view such testing (i.e., increased with African-Americans). These findings have a number of implications for how we will proceed to the next phase of this project, the Survey Phase. We will soon begin the necessary preparation for the pilot testing of the instrument, with subsequent additional refinement. The instrument will then be ready for the commencement of the survey. Additionally in our second year, we will begin the analysis of the data to allow for modeling that will best identify the predictors that would encourage or discourage men from intending to have genetic testing for prostate cancer risk when it becomes available.

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APPENDIX A**Genetic - Prostate Cancer Themes**

Increased Risk	Knowledge of Own Status
Psychological Benefit	Financial Planning
Cancer Prevention	Career Planning
Psychological Distress	Marriage Planning
Stigmatization	Personal Stress
Discrimination	Family Coping
Distress	Prepare for Future Without Guilt
Anxiety	Accommodate Issues
Risk Information	Plan Ahead for Caring
Cancer Related Attitudes and Beliefs	Take Preventative Measures
Use of Health Services	Increased Problems
Changes in Family	Decreased Quality of Life
Changes in Society	Severe Depression
Test Risks	Adversely Affect Marriage
Test Benefits	Mood Enforcement
Test Limitations	Marriage Improvement
Marital Status	Decreased Risk of Children
Education	Level of Functioning
Insurance Status	Social Support Network
Avoidance	Personal Resources
Intrusive Thoughts and Feelings	Clinical Impression
Fertility Behavior	Unprecedented Power
Cancer Related Worry	Management of Risk
Perceived Genetic Risk	Increased Monitoring
Perceived Risk of Cancer	Loss of Job
Stress	Finding a "Pre-existing Condition"
Family Structure	Divide Families
Social Support and Coping	Dash Hope
Ambiguity of "Gene to Cancer" Linkage	Prefer Uncertainty
Life Insurance Risk	Linkage Analysis Need for Multiple Family
What Is "Normal"	Members
Do Genes Have Moral Value?	Ambivalence
Need/Lack of Need for Relative	Urgency if Tested Positive
Counseling - Required vs. Not	Prevent Harm
Gender	Remove Harm
Marital Status	Not Inflict Harm
Number of Children	Promote Good
Education	Right to Know
Occupation	Right Not to Know
Religious Affiliation	Unknown Genetic Linkage to Cancer
Plans for Future	Unknown Relative Risk
For Sake of Children	High Testing Cost
Relieve Uncertainty	Low Treatment Compliance
Plan a Family	Reduce Size of Cancer Prevention Trials
Help Research	Reduce Cost of Cancer Prevention Trials

Provide Information
 Spouse Disclosure
 Relative/Fiancé Disclosure
 Third Party Disclosure
 Denial of Insurance
 Fewer Insured
 State Laws Prohibiting
 Testing/Discrimination
 Savings Through Testing
 Public Education
 Selective Screening
 Mass Screening
 Voluntary Testing
 Test Sensitivity
 Test Specificity
 Positive Predictive Value
 Disease Prevalence
 Intervention Before Validation
 Risk Reduction
 Secondary Prevention
 Respect for Autonomy
 Right to Know
 Duty to Know
 Privacy/Confidentiality
 Truthtelling
 Harm Reduction
 Preserve Family
 Government Intervention
 Removal of Guilt
 Benefit Outweigh Harm
 Prepare for Future
 Improve Life
 Access
 Fairness
 Allocation
 Utilitarianism
 Information Assimilation
 Informational Terms Foreign/Unknown
 Inadequacy
 Impaired Relatedness to Future
 Anxiety
 Anger
 Rejection of God
 Altered Sexual Relationship
 Sense of Purpose
 Ambivalence
 Resolve Interpersonal Conflict
 Resolve Grief Reaction
 Depression
 Suicide
 Decreased Self-Esteem
 Rage
 Personal Identity
 Self Valuation

Sense of Mastery
 Repression
 Denial
 Isolation of Affect
 Punishment of God
 Ethnic Beliefs
 SES Status
 Issue of Burden
 Self Determination
 Genetic Counseling Effectiveness
 Impact on Child Bearing
 Impact on Relationships
 Impact on Marriage/Family
 Abandonment
 Information Release Before Cure Found?
 Avoidance of Suffering
 Need for Control
 Tyranny of the Normal
 Early Detection as a Good
 Cost
 Fear of Cancer
 Faith in Technology
 Survivor Guilt
 Increased Worry
 Concern for Children/Siblings
 Misconceptions of Testing
 Costs of Prophylactic Surgery
 Genetic Determinism
 Fatalism
 Superstition
 Choice
 Trust
 Governmental Misuse
 Forced Testing
 Gene Penetrance
 Test Accuracy
 Disorder Severity
 Family History
 Pretest Information
 Labeling
 Sample Storage
 Types of Referral (minor/3rd party/permission)
 Testing by Insurers
 Testing by Employers
 Physician Knowledge
 Denial of Feelings
 Avoidance of Future Concerns
 Tolerance for Ambiguity
 Rigidity
 Authoritarianism
 Dogmatism
 Ethnocentrism
 Religiosity

Conventionality
Motivation for Testing
When to Screen
Who Will Test
Who Will Counsel
Differential Treatment
Eugenics
Aggressiveness
Sad Mood
Mandatory Testing
Lifestyle Changes
Surveillance
Life Planning
Family Planning
Genetic Reengineering
Coercion
Excitement
Uncertainty
Improvement of Health
Make Informed Choices
Alleviate Fears
Ostracism
Screening Access
Non-directive Counseling
Perceived Risk of Genetic Anomaly
Vigor
Fatigue
Confusion
Reassurance
Improve Personal Health Care

Traumatic Stress
Decisions About Future Marriage
Shock
Understanding/Sympathy
Intensive Screening
Worry
Gladness
Terror
Defect in Gene
Genetic Exculpation
Information Access
Relation to Therapy
Trust
Ambiguity on Results
Complacency
Societal Pressures
Family Pressures
Commercial Pressures
Flawed Nature
Overreaction
Burden of Suffering
Effectiveness of Screening
Potential Harms of Screening
Costs of Screening
Self-Neglect
Denial
Minimization of Risk
Alternative Interventions
Anticipated Outcomes
Concern

APPENDIX B

Focus Group Discussion Guide Prostate Cancer Screening Focus Group

Introduction:

- purpose of discussion
- moderator role
- participant role
- taping/timing
- refreshments/bathrooms

Warm up:

Introductions:

- Name, family composition

In-depth:

As you know, today's discussion is about men's health care. I'd like to hear from each of you regarding your personal attitudes towards preventative care and check-ups.

- Let's go around the room and hear from each of you regarding when you had your last physical examination, and how often you get a physical.

Show Video

Now I want to show you a short video about a particular disease, prostate cancer, and a way of screening for the disease early before it becomes a serious problem.

First thoughts: genetic screening for prostate

- What do you think about genetic testing for prostate cancer using genetic screening?
- What are some of the reasons that a man would seek genetic testing for prostate cancer?

List benefits on flip chart

- What is the biggest benefit you can see to this type of screening for prostate cancer?

List concerns on flip chart

- What kinds of concerns might come up with this testing?

List personal reasons for testing on flip chart

- Based on what you know so far, what would cause YOU to *specifically request genetic screening* beyond the other current screening methods?

Add to reasons flip chart

In addition to these reasons, what other thing might make you personally get a genetic test for prostate cancer risk? [discuss only those not suggested by participants already]:

- How might a family history of prostate cancer change how you feel about genetic testing?
- What if you had personal experience with a relative or an acquaintance who had prostate cancer?
- What if you had a personal history of prostate problems (like infections or benign growths)
- Would test results change your family planning?
- How would your own age effect testing -- Would you be more likely to do testing if you were older or younger?

Influence:

- How much influence would others have on whether you would seek genetic testing?
- How much difference does it make whether your spouse or significant other wants you to have the test or to not have the test?
Is this influence a good or bad thing?
- How much influence do other relatives have on whether you decide to have screening such as:
your brothers/sisters...your children...your doctor...your friends. . .
your reverend/pastor/church leader?

Concerns:

Now I would like to go back to some of the things you mentioned earlier. Let's talk first about the concerns men might have about being tested or genetically screened for prostate cancer. Let's talk about why each of these could be of concern. [Go through list again, then add any concerns not brought up, such as:]

If (+) Test (showing you do have the gene for prostate cancer) :

- Accuracy of the genetic tests/ambiguity of results (not all who test **positive** will get cancer AND many who test **negative** may still get prostate cancer). The test predicts INCREASED RISK to someday get prostate cancer.
- Ways that a positive test would influence how you feel about yourself, how others react to you:
 - Depression, anxiety, loss of hope, etc. [feelings]
 - Reactions of family members -- how would your wife, kids respond to a positive test?
 - Ability to have “healthy” children without the gene(s)
 - Ability to maintain a close relationship with spouse, girlfriend significant other - knowing you may someday get cancer
- How would your life insurance or health insurance respond if or when they find out?
- How would your employers respond if you test positive?
- Confidentiality (Privacy of information) of the test...from family, from insurance companies, from your employers
- Access to the genetic tests - ability of doctor or insurance program to administer the test
- What if your doctor could not order it directly but be required to have a “genetics referral” -
 - with a geneticist and genetics counselor.
 - Transportation to the genetics facility/travel distance from home
 - Amount of time to get counseling for the test and after it is done.
 - Will your insurance likely pay for it? What if they (will/won't)? -- would it change your mind about testing?
 - Cost or inability to pay for the tests

If (-) Test (showing you do not carry the prostate cancer gene(s):

- Ways that a negative test would influence how you feel about yourself, how others react to you -- guilt that you were spared while others you know were not

Regardless of test results

- What if your doctor doesn't recommend getting tested (for some of the reasons we've mentioned so far)
- Wife/girlfriend or other family members oppose your getting tested

Benefits:

OK, let's talk about the positive aspects of genetic screening. Tell me why these benefits are important—refer to benefits list on flip chart—then ask about additional benefits not listed such as:

If (+) Test:

- Early identification of risk -- so you can follow with other screening tests
- Find cancer earlier so you can treat it earlier
- Would it change how you screen (Digital exam/PSA tests) in the future?
 - Planning ahead for future care
 - Would you be better able to plan for future screening?
- More control by knowing whether you have it, detecting it early for treatment:
 - Just knowing and being able to have time to learn about different treatment options
- How about any benefits for families with men who test positive?

If (-) Test:

- Peace of mind/psychological benefits
- Better relationship with spouse, significant other: Could this improve or change your relationship with your spouse?
- Overall improvement of quality of life
- Removal of guilt or worry if tested negative-- Would you feel less worried?
 - Would you feel less guilty about passing the gene on to others?

Regardless of test results:

- Can you see any benefits to doctors and to the field of medicine to have patients get genetic screening for prostate cancer?
- Can you see any benefits to insurance companies for encouraging genetic screening for men?
- For businesses to encourage its male employees to have genetic screening?
- Would it be beneficial to make genetic screening accessible to all adult men who want it?
- How might testing of all men be helpful to society in general?

Summarize & thank

APPENDIX C

Prostate Cancer Genetic Screening Video Script

Hello, my name is Dr. David John Doukas. I am a family doctor and director of this project. I'm here to talk about prostate cancer and the potential role of genetic testing in managing this disease. The prostate gland is the size of a walnut, located just below the bladder, and in front of the anus. The prostate acts like a valve for the urine and semen before it leaves the penis. As men get older, two types of tumors can develop in the prostate - cancerous and noncancerous. When it is cancer, it can spread to organs and tissues around it. It can also enter the blood and be spread to other parts of the body. Prostate cancer is a serious, potentially life-threatening health problem. It is also the most common type of cancer in men. Men are most likely to get prostate cancer if they are over 50 years of age, or have a family history of prostate cancer, or of African-American background.

The usual treatments for prostate cancer are watchful waiting, surgery, or radiation treatment. Watchful Waiting means that no treatment is started, but the patient is examined and checked from time to time. The risks to watchful waiting include growth of the cancer or spread to the rest of the body. Surgery involves surgically removing the entire prostate gland and surrounding tissues to remove the tumor. Sometimes unavoidable injury occurs by the surgery that can lead to impotence (the inability to achieve and maintain an erection) and incontinence (the inability to control one's urine). Radiation Therapy can be used to kill prostate cancer cells. The risks include those mentioned with surgery, as well as bleeding from the bowels. Hormone therapy may also be used to slow the growth of cancer cells and shrink prostate cancer. Sometimes it is necessary to surgically remove the testicles to stop hormone production. However, there is currently not enough data showing whether treatment of prostate cancer helps men live longer.

Four procedures are now used by doctors to find prostate cancer. In the Rectal Examination, the physician inserts a gloved finger into the rectum and examines the prostate gland by checking for lumps or hardness. The PSA (Prostate Specific Antigen) blood test measures the level of a prostate chemical in the bloodstream. If either of these tests is abnormal, further tests may be needed such as ultrasound and biopsy. Ultrasound uses sound waves to look for prostate cancer and help the doctor perform a biopsy. A Biopsy involves removing a small amount of prostate tissue with a needle. The benefits of these screening tests to find prostate cancer are controversial because they are not completely accurate. In the near future we may soon have a new screening test for Prostate Cancer

risk called Genetic Testing. Before discussing this potential new aspect of screening for prostate cancer, I want to discuss the idea of genetic testing broadly.

Information about our physical traits and body functions is organized on our genes. Genes work in many places in the body, including the prostate gland. The genetic changes that lead to prostate cancer may be discovered in the near future.

As the gene or genes associated with prostate cancer are found, a genetic test for prostate cancer risk will likely be developed. It is not clear everyone who tests positive for a prostate cancer gene will develop cancer. Rather, a positive test for a prostate cancer gene will show that a man is at increased risk for developing cancer. There are other factors besides genes, such as your diet, that may cause prostate cancer that we do not fully understand.

We need to understand how men like you will feel about having a genetic test for prostate cancer risk. We want to know your opinions on genetic testing for prostate cancer risk. We want to understand your values, beliefs, and goals about why men may want or not want genetic screening for prostate cancer risk. Your input today will be very helpful for men who may consider this testing in the future.

Thank you for your time and attention.

Slides Shown During Script:

Men at Higher Risk for Prostate Cancer

- Over 50 years old
- Family History of Prostate Cancer
- African-American Background

Usual Treatments For Prostate Cancer

- Watchful Waiting
- Surgery
- Radiation Therapy

- Hormone therapy

Current Tests To Find Prostate Cancer

- Rectal Examination
- Prostate Specific Antigen
- Ultrasound
- Biopsy

Genetic Tests for Prostate Cancer Risk

- Finding the Gene(s)
- Developing a Test
- Other Factors May Also Cause Cancer

APPENDIX D

Major Focus Group Themes and Sub-themes

Beliefs of Consequences . . .

- On insurability
- Will have to continue other forms of prostate testing
- May need further genetic testing as technology develops
- Employment/ability to get promoted could be affected
- Stigmatization of myself
- How will I tell my family?
- Pressure to receive treatment
- Fear of compulsory testing
- Compulsory testing may be helpful for employees and lead to more preventative care
- Truth of knowing test results is good
- Could a positive test lead to precipitous action (for example, prophylactic surgery)?
- Non-traditional health measures may be helpful

Perceived Expectations . . .

- Who pays - HMO/Insurance Co., this is not me
- If no cure currently, why get test?

- If it doesn't detect current cancer - why get the test?
- If a positive test: I can prevent disease by lifestyle changes?
- Medical science will find a cure
- Who should I be seen by: Family Physician vs. Geneticist/specialist

Benefits for Patients . . .

- Cost
- Family planning facilitated
- Society/Medical Science helped through testing
- Truth of knowing what is good
- May expedite finding a cure
- It could save my life
- It will give me peace of mind
- Knowledge could help other family members
- Will lead to more preventative screening tests

Beliefs of Barriers . . .

- Insurability
- Cost: who pays?
- No curative treatment

- Treatment for cancer will hurt my sex life
- Unnecessary surgery will result
- Lack of knowledge
- Decreased quality of life may result
- Accuracy problems of testing
- Self treatment (such as lifestyle changes) are better than physician treatment
- Confidentiality
- Creates worry, anxiety, and stress
- Procrastination could delay testing
- Could this knowledge be used for social or political ends?

Susceptibility Concerns . . .

- Family history
- Current/past behaviors affect susceptibility
- Ethnic background

APPENDIX E

Member Checking Mailing

Dear ^:

Thank you for your recent participation in a focus group on how men view genetic testing for prostate cancer risk. We invited your participation in this research because we believe asking the public about their views will be helpful in the decision making process when the test becomes available.

You had shown a willingness to be contacted about this topic on the feedback form at the end of the focus group. We are now asking for your feedback about this topic to make sure we are accurately summarizing your opinions.

In the near future, genetic screening tests for prostate cancer risk will be developed. By analyzing a person's genes, doctors will be able to estimate a man's future risk of someday developing prostate cancer. This information may prove helpful in understanding the risk of getting prostate cancer. However, due to the very personal nature of genetic testing, there may be new hazards not associated with current screening tests.

Below is our summary of the major issues about genetic screening for prostate cancer you and other men raised during the focus groups. We are asking you now to read this summary, and tell us if you agree or disagree, and then tell us if you think there are other views or opinions we have missed. Please return the summary, with your comments. in the enclosed stamped envelope.

We would very much appreciate your response by August 1. As a "thank you" for your time and contribution, we have included a small gift to express our gratitude. Based on the feedback we receive from you, we will make our final report. Thank you for your help and participation in this project.

Sincerely,

David Doukas, M.D.

Principal Investigator,
Associate Professor of Family Medicine,
University of Michigan

To All Focus Group Participants: The following is a summary of the concerns and beliefs expressed during the twelve focus groups on genetic testing for prostate cancer risk. Of course, not everybody thinks alike, and some ideas have more agreement than others do.

Potential advantages of testing

Men in the focus groups raised many potential benefits of genetic testing. Most men felt that just knowing their test results is a good thing, because more knowledge could help prevent and fight prostate cancer. Testing could be less expensive and more available than other kinds of testing. This test could help society by lowering suffering and speeding up the discovery of a cure. Genetic testing could lead to more, and better, preventive screening tests. It could help couples in their family planning. This testing could save a man's life, and give peace of mind. Also, this knowledge could help other family members. Some felt that testing may be helpful for employees by leading to more preventive care.

Overall Agree Overall Disagree (please circle one)

Comments

Do you have other views or opinions we have missed?

Personal expectations about testing

Among men who were open to having the test, they thought that their HMO or insurance company should pay for it. Among men without insurance, the participating men thought they would only get it if the testing was cheap. Few men without insurance would be willing to pay a "high" price for testing.

The participating men had mixed feelings about the best place to get the test when it is offered — the office of a family doctor or a genetics specialist. Some questioned getting the test at all if it would not detect cancer at the time of testing. Some also questioned the value of testing if the treatment does not increase how long a man lives. Participants voiced their beliefs that if a man were to have a positive test, he could reduce his chances of getting cancer, through such measures as diet, exercise, or other non traditional treatments (such as meditation) to help his chances. Most men would be suspicious if their wives did not want them to have the test, but would be more likely to get the test if their wives wanted them to have testing.

Overall Agree Overall Disagree (please circle one)

Comments

Do you have other views or opinions we have missed?

Disadvantages of Testing

It is possible there will be important disadvantages to genetic testing. Testing could possibly affect a man's eligibility for, and cost of, health or life insurance. The testing could have accuracy problems and not find the gene or falsely identify a good gene as bad. As a result, a man's quality of life could be affected for the worse just by getting tested. For some men, getting tested could create worry, anxiety, and stress. If a man were to get treatment for cancer based on this test, the treatment could hurt his sex life. Required testing may someday be used for job or insurance purposes.

Overall Agree Overall Disagree (please circle one)

Comments

Do you have other views or opinions we have missed?

Consequences of Testing

The consequences of genetic testing for prostate cancer risk raises concerns for men. This testing could cause privacy problems, especially with insurance companies, employers, and family members wanting to know the results. Some men questioned whether genetic testing could someday be used for some social or political aims. The ability to buy insurance, get a job, or get a promotion could be worse after a positive test. A man's image of himself could be lowered by a test showing a prostate cancer gene. Even if a man has the genetic test, he might still need to be regularly screened. Also, he will need to get additional genetic testing as science finds new genetic discoveries. Men could be pressured into cancer treatment that they do not want. Fear could even drive some men into sudden action like preventive removal of the prostate.

Overall Agree Overall Disagree (please circle one)

Comments

Do you have other views or opinions we have missed?

Concerns Based on My Background

A man's concerns about the risk of getting prostate cancer will be based on whether he has a family history of prostate cancer, his overall current and past health behavior, as well as his ethnic background.

Overall Agree Overall Disagree (please circle one)

Comments

Do you have other views or opinions we have missed?

Observations about Different Groups

Older men tended to be more interested in getting genetic screening for prostate cancer. Caucasians and African American men were more suspicious of the government and companies using testing in potentially harmful ways. Asian American men were the least suspicious of disadvantages of testing.

Overall Agree Overall Disagree (please circle one)

Comments

Do you have other views or opinions we have missed?

Other General Comments:

THANK YOU FOR YOUR PARTICIPATION!

Appendix F

Prostate Cancer Genetic Testing Questionnaire Instructions

Thank you for agreeing to complete the following questionnaire. Please do not leave any items blank. All of your responses will be kept strictly confidential and will not be made available to anyone but study investigators. Once completed - please fold, and return it to the research assistant. We are interested in your personal beliefs.

Part One

Listed below are a number of concepts which reflect patient concerns regarding new potential genetic screening for prostate cancer risk. We are interested in how you would evaluate each of these concepts as to how favorable or unfavorable each is, and how much they each would influence your decision to receive a genetic test for prostate cancer risk.

Under each of these medical concerns you will see a seven point scale. Please circle the number in the direction that most strongly reflects your feelings about each of the medical concerns you are judging. There are no right or wrong answers. We are interested in your own feelings and beliefs about these medical concerns in genetic testing.

Again, please remember, we are interested in how you would evaluate each of these concepts if you had the opportunity to receive a genetic test for prostate cancer risk.

Please turn the page over when done reading this page.

On the following 7 point scales, please circle the numbers that best reflects your perception on each medical concern below.

My receiving a genetic screening test for prostate cancer would depend on . . .

	Favorable							Unfavorable							Influences Me Very Strongly							Does Not Influence Me at All						
	1	2	3	4	5	6	7	1	2	3	4	5	6	7	1	2	3	4	5	6	7	1	2	3	4	5	6	7
1...My ability to get health insurance																												
2...My ability to get life insurance																												
3...The chances it will hurt my getting a job																												
4...The chances it will hurt my getting a promotion																												
5...How I would feel about myself																												
6...How I view it will change how people will feel about me																												
7...How it will strain my family																												
8...The need to still get other prostate tests.																												
9...How it helps me know my risk																												
10...How I view that I have some over getting prostate cancer																												
11...My views of having a better of cure																												
12...My family physician's approval of the test																												
13...My relatives' approval of the test																												
14...My friends' approval of the test																												
15...A geneticist's approval of the test																												
16...My health care plan paying for it																												
17...My family physician would provide me counseling																												
18...My views on family planning																												
19...My view that testing will benefit everyone																												
20...My view that testing could save my life																												

21...My view that testing could ruin my sex life	1 2 3 4 5 6 7	1 2 3 4 5 6 7
22...My view that testing would give me peace of my mind	1 2 3 4 5 6 7	1 2 3 4 5 6 7
23...My view that knowing the test results will hurt my quality of life	1 2 3 4 5 6 7	1 2 3 4 5 6 7
24...My view that testing will just make me worry	1 2 3 4 5 6 7	1 2 3 4 5 6 7
25...My view that testing would delay my treatment	1 2 3 4 5 6 7	1 2 3 4 5 6 7
26...My view that testing would affect my family	1 2 3 4 5 6 7	1 2 3 4 5 6 7
27...My family history	1 2 3 4 5 6 7	1 2 3 4 5 6 7
28...My current health behavior	1 2 3 4 5 6 7	1 2 3 4 5 6 7
29...My ethnic	1 2 3 4 5 6 7	1 2 3 4 5 6 7

....My view that testing raise privacy concerns regarding the following persons:

30...My employer	1 2 3 4 5 6 7	1 2 3 4 5 6 7
31...Insurance Company	1 2 3 4 5 6 7	1 2 3 4 5 6 7
32...Government	1 2 3 4 5 6 7	1 2 3 4 5 6 7
33...Family	1 2 3 4 5 6 7	1 2 3 4 5 6 7
34...Friends	1 2 3 4 5 6 7	1 2 3 4 5 6 7

Part Two

We would like to know a few things about you. Please place an X by your answer to each question or fill in the blank.

35. What is your year of birth: _____

36. Indicate your marital status:(mark one)

- ☐ Single
☐ Living with a "significant other"
☐ Married
☐ Separated or Divorced
☐ Widowed

With whom else do you live (please mark all that apply)

- ☐ Child(children) under 18 years old
☐ Child(children) over 18 years old
☐ Parent(s)
☐ Brother/sister(s)
☐ Other family members(s)
☐ Friend(s)

37. Indicate your ethnic background:

- ☐ Caucasian/Non-Hispanic White
☐ African-American
☐ Hispanic
☐ Asian
☐ Indian Subcontinental
☐ American Indian

37. How many children do you have? _____

If you have children, what are their ages? _____

38. Please circle the highest number of years of education you have completed:

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	20+
											^				^				^	
											High				College				Graduate	
											school				degree				degree	
											diploma									

39. Indicate your household's approximate yearly income: (check one)

- ☐ \$0 to 15,000
☐ \$15,001 to 30,000
☐ \$30,001 to 45,000
☐ \$45,001 to 60,000
☐ \$60,001 to 75, 000
☐ \$75, 001 to 90,000
☐ over \$90,000

40. To what religious denomination do you belong? _____

41. What is the zip code of your home address? _____

42. Are you currently employed?

☐ Yes

IF Yes, What is your occupation? _____

☐ No

IF No, Are you:

☐ Retired

☐ Unable to work because of your health

What was your occupation when you were working?

43. Have you been admitted to the any hospital in the last 6 months?

☐ No

☐ Yes If Yes, how many times were you in the hospital? _____

44. Which of the following best describes your health? (please mark one with an X)

☐ excellent

☐ good

☐ fair

☐ poor

45. Which of the following best describes your current health insurance coverage (please mark with an X all that apply).

☐ managed care organization

☐ private insurance

☐ Medicaid

☐ Medicare

☐ not sure

☐ self-pay

☐ other

46. Have you ever had any of the following (please mark with an X all that apply)

- ☐ prostatitis (infection of the prostate)
- ☐ enlarged prostate (BPH-benign prostatic hypertrophy)
- ☐ prostate cancer
- ☐ other cancer (please write in the type(s) below):
- ☐ none of the above
- ☐ don't know

47. Which of the following affected someone in your family. Family includes: grandfather, father, brother, son? (please mark with an X all that apply).

- ☐ prostatitis (infection of the prostate)
- ☐ enlarged prostate (BPH or benign prostatic hypertrophy)
- ☐ prostate cancer
- ☐ none of the above
- ☐ don't know

48. Which of the following cancers have occurred in your family. Family includes: grandparents, parents, siblings, children? (please mark with an X all that apply).

- | | |
|---------------------------------------|--|
| <input type="checkbox"/> testicular | <input type="checkbox"/> colon or rectal |
| <input type="checkbox"/> lung | <input type="checkbox"/> throat or nose |
| <input type="checkbox"/> breast | <input type="checkbox"/> cervical or uterine |
| <input type="checkbox"/> ovarian | <input type="checkbox"/> skin |
| <input type="checkbox"/> other cancer | <input type="checkbox"/> don't know |

Thank you for your help in this survey. If you have any questions or comments for us, please write them here.